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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,607	04/27/2006	W. Charles O'Neill	050508-1400	5401

24504 7590 04/12/2010

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EXAMINER	
KASSA, TIGABU	

ART UNIT	PAPER NUMBER
1619	

MAIL DATE	DELIVERY MODE
04/12/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,607	O'NEILL ET AL.	
	Examiner	Art Unit	
	TIGABU KASSA	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 9-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 9-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the amendment filed on October 30, 2009. Claim 1-5 and 9-16 are pending and are under consideration in the instant office action. Claims 6-8 and 17-34 are cancelled. Applicant's amendment has necessitated a new ground of rejection. Accordingly, this Action is FINAL.

Withdrawn rejections

Applicant's amendments and arguments filed on 10/30/09 are acknowledged and have been fully considered. All rejections applied in the previous office action are hereby withdrawn as a result of applicants claim amendments.

New Rejections

Claim Rejections - 35 USC § 112

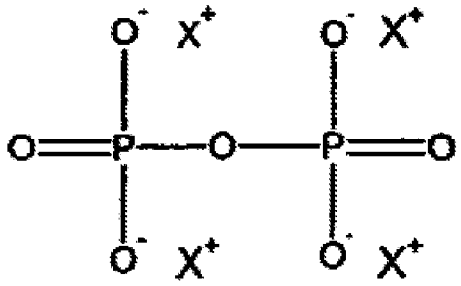
The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention .
>
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: The structure of the pyrophosphate compound, wherein X is chosen from at least one of a hydrogen and a cation. The

examiner considered for art rejections the structure to mea n as filed in the original claim set



The above structure appears to have been **have been inadvertently omitted from the claim set of 08/-7/2009, which omission appears to be duplicated in the instant claim set filed on 10/30/2009. Applicant, in response to this action, is required to clarify the language of claim 9. Applicant is reminded that MPEP 714 instructs:** Amendments to a claim must be made by rewriting the entire claim with all changes (*e.g.*, additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibition of calcification in human subjects as disclosed in the specification page 22, lines 4-5, does not reasonably provide enablement for prophylactically treating vascular calcification human subjects.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope of breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1) Scope or breadth of the claims

The examiner construed prophylactically treating to mean "preventing" since the Compact Oxford English Dictionary teaches that prophylaxis is "action taken to prevent disease. Preventing is interpreted to mean hundred percent inhibition since the Compact Oxford English Dictionary teaches that prevention is to keep from happening or arising.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims as set forth below.

2) Nature of the invention

The nature of the invention is directed to a slimming composition and method of reducing or lowering excess body fat in human subjects.

3) Relative level of skill possessed by one of ordinary skill in the art

The relative level of skill possessed by one of ordinary skill in the art of medical research is relatively high, as a majority of lead investigators conducting scientific research and development in this particular area possess M.D. and/or Ph.D. in a scientific discipline such as medicinal chemistry, biochemistry, pharmacology, biology, organic synthetic chemistry or the like.

4) State of, or the amount of knowledge in, the prior art

The art teaches that the pyrophosphate being an inhibitor of vascular calcification Lomashvili et al. (J Am Soc Nephrol 2005, 16, 2495-2500; IDS reference). **Pyrophosphate is an inhibitor of vascular calcification and vascular calcification cannot occur in the presence of normal concentrations of pyrophosphate** (page 2495, second paragraph).

5) Level or degree of predictability, or lack thereof, in the art

A high degree of unpredictability existed in the state of the prior art regarding how to prevent vascular calcification. As the prior art indicates above it is possible to treat vascular calcification. However, Lomashvili et al. (J Am Soc Nephrol 2005, 16, 2495-2500; IDS reference) also teach that other factors such as hyperphosphatemia also

play a role in vascular calcification. Additionally, further studies will be necessary to determine whether correction of the pyrophosphate deficiency in hemodialysis patients will reduce vascular calcification (p 2499, last paragraph).

6) Amount of guidance or direction provided by the inventor and 7) Presence or absence of working examples

The instant specification discloses for inhibition of calcification in cultured rat aortas and also has examples of addition of pyrophosphate to dialysis solution for human subjects.

The specification fails to provide scientific data and working embodiments with respect to prevention of vascular calcification. In fact, the working examples with human subjects merely state the addition of the pyrophosphate to the dialysis solution and does not provide a discussion of the effect on the vasculature of the human subjects.

8) Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

As a result of the lack of working examples and guidance for preventing vascular calcification, one of ordinary skill in the art would be required to conduct an undue amount of experimentation, to reasonably and accurately determine whether the method of the instant application does in fact prevent vascular calcification. Since Lomshivili et al. teach that pyrophosphate deficiency is likely not the sole cause of vascular calcification, correction of pyrophosphate deficiency alone cannot be expected to prevent vascular calcification caused by other factors such as hyperphosphatemia. Moreover pyrophosphate may also be protein bound and it is not know whether the protein bound form would inhibit vascular calcification. Since addition of pyrophosphate to dialysate

does not control the proportion of protein bound pyrophosphate, addition of pyrophosphate to dialysis solution does not necessarily prevent vascular calcification caused by pyrophosphate deficiency.

In conclusion, it is readily apparent from the aforementioned disclosure, in conjunction with the lack of scientific data and working embodiments regarding the prevention of vascular calcification, one of ordinary skill in the art would therefore be required to conduct an undue amount of experimentation to reasonably and accurately extrapolate whether said method would prevent vascular calcification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 11-14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Gupta et al. (Kidney International 1999, 55, 1891-1898).

Instant claim 1 recites a method of providing vascular calcification therapy to a human in need of treatment comprising the step of administering to a human during dialysis having an effective amount of a pyrophosphate-type compound, wherein the human has renal disease failure. Instant claim 5 recites the method of claim 1 wherein the vascular calcification is caused by renal disease or failure. Instant claims 9 recites the method of claim 1, wherein the pyrophosphate-type compound has a structure as recited

in the claim. Instant claims 11-13 recite the concentrations of the pyrophosphate compound. Instant claim 14 recites a method of prophylactically treating vascular calcification comprising administering to a human in need of treatment an effective amount of at least one pyrophosphate-type compound. Instant claim 16 recites the method of claim 14, wherein pyrophosphate-type compound is administered to the individual in a dialysate.

Gupta et al. disclose the addition of **iron pyrophosphate to dialysate during dialysis**. Gupta et al. disclose that **the patient population being human by stating that informed consent was obtained from 24 patients with end-stage renal disease receiving maintenance hemodialysis for at least three months** (see p 1892 under study design). Gupta et al. disclose that first a stable and clear dialysate solution containing up to 71 mg/dl iron as ferric pyrophosphate was generated (see p 1892 under hemodialysis with solutions containing ferric pyrophosphate). Gupta et al. disclose that in their study they use an initial dialsyate iron concentrations of 2 μg/dl, which was increased every four weeks to 4, 8, and then to a maximum of 12 μg/dl. The examiner correlates the concentration of iron to pyrophosphate considering ferric pyrophosphate has a formula of $Fe_4(P_2O_7)_3$. Based on the examiner calculation the maximum 12 μg/dl of iron in the solution correlates to 1.6 μM of pyrophosphate which clearly anticipates the limitations of instant claims 11-13. The examiner notes that applicant did not define what the term "about" constitute. Therefore, the examiner contends that 1.6 μM is about 3 μM.

The examiner construed the recitations in the preamble both in instant claims 1 and 14 stating a method of "providing vascular calcification therapy to a human" and a method of "prophylactically treating vascular calcification", respectively, as intended use.

A preamble is generally not accorded any patentable weight where it **merely recites the purpose of a process or the intended use of a structure**, and where the body of the claim does not depend on the preamble for completeness but, instead, **the process steps or structural limitations are able to stand alone**. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In the instant case, the patient population (human) and the step of administrating pyrophosphate compound are the same between Gupta et al. and the instantly claimed invention. Therefore, the limitations of instant claims 1, 5, 11-14, and 16 are clearly anticipated by the teachings of Gupta et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 9, 11-14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lomashvili et al. (J Am Soc Nephrol 2005, 16, 2495-2500; IDS reference) in view of Gupta et al. (Kidney International 1999, 55, 1891-1898) and Russell et al. (The Journal of Clinical Investigation 1971, 50, 961-969).

Applicant Claims

Instant claim 1 recites a method of providing vascular calcification therapy to an individual in need of treatment comprising the step of administering to a human an effective amount of a pyrophosphate-type compound. Instant claim 5 recites the method of claim 1 wherein the vascular calcification is caused by renal disease or failure. Instant claims 9 recites the method of claim 1, wherein the pyrophosphate-type compound has a structure as recited in the claim. Instant claims 11-13 recite the concentrations of the pyrophosphate compound. Instant claim 14 recites a method of prophylactically treating vascular calcification comprising administering to a human in need of treatment an effective amount of at least one pyrophosphate-type compound. Instant claim 16 recites

the method of claim 14, wherein pyrophosphate-type compound is administered to the individual in a dialysate.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Lomashvili et al. teach vascular calcification is common in patients with end stage renal disease (page 2495, first paragraph)**. Pyrophosphate is an inhibitor of vascular calcification and vascular calcification cannot occur in the presence of normal concentrations of pyrophosphate** (page 2495, second paragraph). **Pyrophosphate levels are reduced in hemodialysis patients** (abstract). Pyrophosphate is removed during dialysis (page 2497, section Dialytic clearance of PPi). **Pyrophosphate deficiencies may cause vascular calcification; additional studies are necessary to determine whether correction of the pyrophosphate deficiency in hemodialysis patients will reduce vascular calcification** (page 2499, last paragraph).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Lomashvili et al do not explicitly teach the addition of pyrophosphate to dialysis dialysate. This deficiency is cured by Gupta et al and Russell et al.

The teachings of Gupta et al are set forth above.

Russell et al teach the concentration of pyrophosphate in plasma in normal persons is 3.5 μmols/liter (3.5 μM) (see page 967 first column paragraph 2).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to add pyrophosphate dialysate for hemodialysis patients and thus produce the instantly claimed invention since Gupta et al. teach the addition of

pyrophosphate to dialysis solutions and since Lomashvili et al. teach that pyrophosphate deficiencies may cause vascular calcification. An ordinary skilled artisan would have been motivated to add pyrophosphate to the dialysate to avoid removing pyrophosphate during dialysis. Since the pyrophosphate moves down its concentration gradient across the semipermiable membrane used in hemodaialysis the pyrophosphate would be removed under hemodialysis conditions in which the dialysate does not contain pyrophosphate. Addition of pyrophosphate to the dialysate would be expected to correct this effect. One of ordinary skill in the art at the time of the instant application was filed would have had a reasonable expectation of success in adding pyrophosphate to dialysate since Gupta et al. explicitly teaches the addition of pyrophosphate to dialysate. The examiner notes that although Gupta et al. teaches the addition of iron pyrophosphate to correct iron deficiencies and not pyrophosphate deficiencies, it would still have been obvious to the skilled artisan that addition of solutes to the dialysate can be used to correct detrimental loss of those solutes from the plasma of the hemodialysis patient. Moreover, it specifically teaches that pyrophosphate may be successfully added to dialysate. Additionally, Lomashvili et al. already teaches the connection between plasma pyrophosphate concentrations in hemodialysis patients and vascular calcification.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to add the pyrophosphate at a concentration of around 3.5 μM and thus produce the instantly claimed invention since Russell et al. teach the normal level of pyrophosphate plasma is 3.5 μM. An ordinary skilled artisan would have been motivated to add the pyrophosphate to the dialysate at a concentration of 3.5 μM in order to optimize the level of pyrophosaphte in the blood of the dialysis patient. The examiner

notes that since the pyrophosphate moves down its concentration gradient across the semipermiable membrane used in dialysis it would have been obvious to the skilled artisan to select the normal concentration of pyrophosphate in human blood plasma as the appropriate concentration of pyrophosphate to add to the dialysate. One of ordinary skill in the art at the time of the instant application was filed would have had a reasonable expectation of success in adding the pyrophosphate to the dialysate since Gupta et al. already teaches the addition of pyrophosphate to dialysate and the normal plasma levels of pyrophosphate are thought by Russell et al.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Claims 1-4, 9-10 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lomashvili et al. (J Am Soc Nephrol 2005, 16, 2495-2500; IDS reference) in view of Gupta et al. (Kidney International 1999, 55, 1891-1898) and Sommer (A text of inorganic chemistry, Herbert Hayward, 1906).

Applicants' claims

Instant claim 2 recites the method of claim 1, wherein the pyrophosphate-type compound is an alkali metal pyrophosphate. Instant claim 3-4 recite the method of claim 1, wherein the pyrophosphate-type compound is chosen from the lists recited in the claims. Instant claims 9 recites the method of claim 1, wherein the pyrophosphate-type

compound has a structure as recited in the claim. Instant claim 10 recites the method of claim 9 wherein X is chosen from the instantly claimed list. Instant claim 15 recites the method of claim 14, wherein the pyrophosphate-type compound is an alkali metal pyrophosphate.

Determination of the Scope and Content of the Prior Art

(MPEP 2141.01)

The references of Lomashvili et al. (J Am Soc Nephrol 2005, 16, 2495-2500; IDS reference), Gupta et al. (Kidney International 1999, 55, 1891-1898) and Russell et al. (The Journal of Clinical Investigation 1971, 50, 961-969) are discussed in detail above and that discussion is hereby incorporated by reference.

Ascertainment of the Difference Between Scope of the Prior Art and the Claims

(MPEP 2141.02)

Lomashvili et al., Gupta et al., and Russell et al. do not specifically teach the pyrophosphate salts of sodium, potassium, calcium or phosphoric acid. This deficiency is cured by Hayward.

Hayward et al. teach that iron pyrophosphate is insoluble in water and that sodium pyrophosphate is soluble in water.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP 2142-2143)

It would have been obvious to the skilled artisan at the time the present invention was made to add the pyrophosphate as sodium pyrophosphate and thus produce the instantly claimed invention since sodium pyrophosphate is more soluble than iron pyrophosphate. The skilled artisan would be motivated to select sodium pyrophosphate so

that the pyrophosphate would be soluble in the dialysate which is very critical. The skilled artisan would have a reasonable expectation of success since sodium pyrophosphate is soluble in water and is therefore expected to be soluble in dialysate.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Claims 1-5 and 9-16 are rejected. Claims 6-8 and 17-34 are cancelled. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne P. Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa 03/12/10

/YVONNE L. EYLER/

Supervisory Patent Examiner, Art Unit 1619